

### III. REMARKS

This document is being submitted in response to the final Office Action issued by the Patent Office on June 16, 2009. In the present application, claims 1, 2 and 12-19 are pending, claims 12 and 13 have been withdrawn from consideration, and claims 1, 2 and 12-19 stand as rejected by the Patent Office. The Applicant respectfully traverses the rejection of the claims in the present Office Action, and for the reasons stated below respectfully requests that the Patent Office withdraw these rejections and allow all pending claims.

#### Rejections under 35 U.S.C. §103(a)

On pages 2-3 of the Office Action of June 16, 2009, the Patent Office states that claims 1, 2, 14, 16, 17 and 18 are rejected under 35 U.S.C. §103(a) as being unpatentable over Silverstein *et al.* (U.S. Pat. No. 5,025,778), hereinafter referred to as Silverstein, in view of Henniges *et al.* (U.S. Patent App. No. 2002/0058914), hereinafter referred to as Henniges. On pages 3-4 of the Office Action, the Patent Office states that claims 15 and 19 are rejected under 35 U.S.C. §103(a) as being unpatentable over Silverstein in view of Majlessi (U.S. Pat. No. 4,842,583). For at least the reasons stated below, the amended claims are believed to define patentably over the §103 references cited by the Patent Office and over the prior art in general.

The following principles of law apply to all Section 103 rejections. MPEP §2141.02 (VI) states, “[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).” [Emphasis in original]. MPEP §2143.02 provides, “[o]bviousness does not require absolute predictability, however, at least some degree of predictability is required. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976).” MPEP §2143.03 provides “[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art. *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 USC 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).” Further,

MPEP §2145(X)(D)(2) states, “[t]he totality of the prior art must be considered, and proceeding contrary to accepted wisdom in the art is evidence of nonobviousness. *In re Hedges*, 783 F.2d 1038, 228 USPQ 685 (Fed. Cir. 1986).” In the present case, the cited references clearly do not teach some limitations of the Applicant's claims, and in some instances actually teach away from the invention as claimed. The Applicant argues that the pending claims (as written), do not permit a finding of *prima facie* obviousness in the present application because the cited art does not teach nor suggest all the claim limitations of the Applicant's claimed invention, and/or there is no reasonable expectation of success in combining the teachings of the cited references.

The Applicant argues that Silverstein and Henniges do not, either individually or in combination, teach nor suggest all of the Applicant's claim limitations as required by MPEP 2142 for a finding of obviousness. As clearly stated in the preamble to each pending claims, the Applicant's claimed device is intended for use in colon hydrotherapy and is not an endoscope or surgical device of any kind. The Applicant's claimed device is manufactured from a rigid material such as plastic or polymer (see paragraph [0023] of the Applicant's specification) and is designed to deliver a high-pressure fluid vortex to remove impacted fecal matter from a patient's colon. The nozzle of the Applicant's claimed device includes a plurality of trapezoidal outlets which produce the high-pressure vortex. None of these features of the claimed invention are taught or suggested by any of the cited references, and combining what is taught by the cited references would not result in any type of effective colon hydrotherapy device.

Silverstein teaches a flexible endoscope which is intend for internal examination of various areas of the human body (see column 1, lines 25-40) and there is nothing in this reference that suggests that the described device would be suitable for colon hydrotherapy, which utilizes a different type of device entirely. Any discussion of the use of fluid with Silverstein's device is limited to a low-pressure introduction of fluid (see column 7, lines 1-12), which would be inadequate for purposes of removing impacted fecal matter from the colon. There is no suggestion of any type of high-pressure fluid vortex, such as that claimed by the Applicant, in Silverstein. Henniges teaches a surgical irrigator that is also not suitable for colon hydrotherapy. The U-shaped channels shown in FIG. 10 of Henniges are clearly not trapezoidal, as claimed by

the Applicant, nor are they operative to create a high pressure vortex of water capable of removing impacted fecal matter from the colon. Simply put, neither of the devices taught by Silverstein and Henniges have anything to do with colon hydrotherapy and neither is suitable for such an application; therefore, one of ordinary skill in the art would not be motivated to combine the teachings of these references to arrive at the claimed colon hydrotherapy device. Because multiple features of the claimed invention are missing from both Silverstein and Henniges, and because these two references cannot be combined to teach an effective or functioning colon hydrotherapy device, these references cannot support a finding of obviousness under 35 U.S.C. §103(a). Therefore, the Applicant argues that independent claims 1 and 16 and all of their dependent claims (including claims 15 and 19) are patentable over the cited references and the rejection of these claims under 35 U.S.C. §103(a) should be withdrawn.

#### Conclusion

In light of the arguments presented herein, the Applicant asserts that the pending claims are not obvious in view of the cited references and that these claims define patentably over the art cited by the Patent Office and over the prior art, in general. For at least the reasons set forth herein, this application is believed to be in condition for allowance and favorable reconsideration is respectfully requested.

Respectfully submitted,

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